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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/661,070	02/26/91	HUSTON J	CRP-008

EXAMINER
ULM, J

ART UNIT	PAPER NUMBER
185	9

DATE MAILED: 09/20/91

PAUL LUNN
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4-29-91 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Petent Application, Form PTO-152.
5. ☐ Informstion on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 27 to 46 are pending in the application.
   Of the ebove, claims 39 to 46 are withdrawn from consideretion.
2. ☒ Claims 1 to 26 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 27 to 38 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which ere ecceptable for examination purposes.
8. ☐ Formal drewings are required in response to this Office action.
9. ☐ The corrected or substitute drawings heve been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ eccepteble. ☐ not acceptebie (see explenetion or Notice re Petent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the exeminer (see explenation).
11. ☐ The proposed drewing correction, filed on _____, has been ☐ epproved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is mede of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appeers to be in condition for allowence except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Claims 27 to 46 are pending in the instant application with claims 1 to 26 having been canceled as requested in Applicant's Preliminary Amendment A.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 27 to 38, drawn to a fused polypeptide, classified in Class 530, subclass 350.

II. Claims 39 to 44, drawn to a method of making a bifunctional analog of a natural protein by recombinant DNA techniques, classified in Class 435, subclass 69.7.

III. Claims 45 and 46, drawn to a bifunctional analog of a natural protein, classified in Class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Invention I is not inherently related to Inventions II and III.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product claimed can be made by a materially different process such as chemical synthesis.

Because these inventions are distinct for the reasons given

above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Edmund Pitcher on 16 September of 1991 a provisional election was made with traverse to prosecute the invention of group I, claims 27 to 38. Affirmation of this election must be made by applicant in responding to this Office action. Claims 39 to 46 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which

the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 27 to 38 are rejected under 35 U.S.C. § 103 as being unpatentable over the Cousens et.al. (1A) patent in view of the Cohen et.al.(1B) patent. These claims are drawn to a fused polypeptide comprised of a leader sequence that facilitates purification, a cysteine-free hinge region, a selected cleavage site, and a target polypeptide. The Cousens reference anticipates the claimed invention in its entirety except that it does not specifically state that cysteine residues are to be omitted from the hinge region. The Cohen references shows that it was known in the art of fusion protein construction that "the

elimination of cysteine residues in the leader peptide [of a fusion protein] prevents possible interactions and interferences with the obligatory formation of disulfide bridges in the active analogs" (the target polypeptide). To construct a fusion protein like the one described in the Cousens reference without cysteine residues in the hinge region as advised in the Cohen reference was fairly taught in the art prior to the making of the instant invention.

Any inquiry concerning this communication should be directed to John D. Ulm at telephone number (703) 308-1906.

RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 185